

## Clinical Policy: Outpatient Oxygen Use

Reference Number: CP.MP.190 Date of Last Revision: 01/24 Effective Date: 07/01/24 Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

#### **Description**

Oxygen therapy is the administration of oxygen at concentrations greater than that in ambient air (20.9%) with the intent of treating or preventing the symptoms and manifestations of hypoxemia.<sup>1</sup>

Note: If a medically necessary, lesser cost item exists and will suit the member/enrollee's medical needs, a higher cost item will be denied.

#### Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that initial approval of oxygen concentrators and oxygen systems (for indications other than cluster headaches; for stationary oxygen systems for cluster headaches, see section VI) for members/enrollees ≥ 18 years of age are **medically necessary** when meeting all of the following<sup>8</sup>:
  - A. Physician-documented severe lung disease or hypoxemia-related symptoms that might be expected to improve with oxygen therapy;
  - B. The blood gas study meets one of the following:
    - 1. Member/enrollee qualifies for Group I by meeting any of the following<sup>3,8</sup>:
      - a. An arterial PO<sub>2</sub> at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent taken at rest (awake), breathing room air;
      - b. An arterial PO<sub>2</sub> at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep, for a beneficiary who demonstrates an arterial PO<sub>2</sub> at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake;
      - c. A decrease in arterial PO<sub>2</sub> more than 10 mm Hg, or a decrease in arterial oxygen saturation more than five percent from baseline saturation, taken during sleep and associated with symptoms (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia) or signs (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension, and erythrocytosis) reasonably attributable to hypoxemia;
      - d. An arterial PO<sub>2</sub> at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a beneficiary who demonstrates an arterial PO<sub>2</sub> at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the beneficiary was breathing room air;
    - 2. Member/enrollee qualifies for Group II by meeting both of the following<sup>1,8</sup>:
      - a. An arterial PO<sub>2</sub> of 56 through 59 mm Hg or an arterial blood oxygen saturation of 89 percent or less at rest (awake), during sleep, or during exercise (as described under Group I criteria);

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- b. Any of the following:
  - i. Dependent edema suggesting congestive heart failure;
  - ii. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF);
  - iii. Erythrocythemia with a hematocrit greater than 56 percent;
- C. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services<sup>3,8</sup>;
- D. The qualifying blood gas study was obtained under one of the following conditions<sup>3,8</sup>:
  - 1. Performed during an inpatient hospital stay, and the reported test was the one obtained closest to, but no earlier than two days prior to the hospital discharge date;
  - 2. Not performed during an inpatient hospital stay, and the reported test was performed when the treating practitioner noted signs and symptoms of illness that can be relieved by oxygen treatment in the home;
- E. If the request is for a portable oxygen system, both of the following<sup>8</sup>:
  - 1. The member/enrollee is mobile within the home or community;
  - 2. The qualifying blood gas study was performed while at rest (awake) or during exercise. (If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not reasonable and necessary).
- II. It is the policy of health plans affiliated with Centene Corporation that initial approval of oxygen concentrators and other oxygen delivery systems for members/enrollees < 18 years of age (including medically fragile members/enrollees and those covered under EPSDT) are medically necessary when meeting all of the following<sup>5</sup>:
  - A. Physician-documented severe lung disease or hypoxemia-related symptoms that might be expected to improve with oxygen therapy, including but not limited to the following:
    - 1. Chronic lung disease of prematurity;
    - 2. Cystic fibrosis complicated by severe chronic hypoxemia<sup>5</sup>;
    - 3. Acute pulmonary/respiratory disease with persistent type I (hypoxic) respiratory failure, as a means to facilitate earlier discharge to home, when deemed safe;
    - 4. Bronchopulmonary dysplasia (BPD) complicated by chronic hypoxemia<sup>5</sup>;
    - 5. Agenesis, hypoplasia, dysplasia of the lung;
    - 6. Chronic cardiopulmonary disease (cor pulmonale);
    - 7. P pulmonale (right atrial enlargement) on EKG;
    - 8. Any of the diagnostic causes of chronic hypoxemia due to alveolar hypoxentilation, ventilation-perfusion mismatching, intracardiac or intrapulmonary shunting, or impaired alveolar-capillary diffusion;
    - 9. Pulmonary hypertension without congenital heart disease (CHD) complicated by chronic hypoxemia<sup>5</sup>;
    - 10. Interstitial lung disease complicated by severe chronic hypoxemia<sup>5</sup>;
  - B. Laboratory results of oximetry, polysomnography, or arterial blood gases demonstrate one of the following<sup>5</sup>:
    - 1. In children younger than one year old, one of the following:
      - a.  $SpO_2 \le 90\%$  during 5% of the recording time;

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- b. Three independent measurements of  $SpO_2 \le 90\%$  if measurements are taken intermittently;
- 2. In children aged one year or older, one of the following:
  - a. SpO<sub>2</sub>  $\leq$  93% during 5% of the recording time;
  - b. Three independent measurements of  $SpO_2 \le 93\%$  if measurements are taken intermittently;
- C. If request is for a portable oxygen system, member/enrollee is mobile within the home or community.<sup>7</sup>
- III. It is the policy of health plans affiliated with Centene Corporation that reauthorization of oxygen concentrators and oxygen systems for members/enrollees  $\geq 18$  years of age are **medically necessary** when meeting the following<sup>1,7,9</sup>:
  - A. Evaluation by the treating physician within 90 days prior to the date of recertification, and one of the following:
    - 1. Chronic hypoxemia is not expected to improve or is expected to worsen, as documented in an explanatory letter of medical necessity (LOMN);
    - 2. Treatment is for nocturnal hypoxemia in a member/enrollee who qualifies for Group I (as defined in criteria section I), and two oxygen requests have already been authorized;
    - 3. A new arterial blood gas (ABG) or pulse oximetry result documents that member/enrollees still meets the criteria in section I above (initial approval criteria), and one of the following:
      - a. For Group I (as defined in section I), the measurement is obtained within 90 days of the recertification date, and by the physician or designee, or by an independent diagnostic testing facility (IDTF). O<sub>2</sub> levels obtained by DME providers do not qualify. Home oxygen companies are permitted to coordinate with an IDTF for the purpose of obtaining needed overnight oximetry saturation testing;
      - b. For Group II (as defined in section I; rare cases where initial certification was for three months with PO<sub>2</sub> 56 through 59 or O<sub>2</sub> sat 89%), a repeat ABG or oximetry must be obtained within 30 days of recertification date;
  - B. If the request is for a portable oxygen system, both of the following<sup>7</sup>:
    - 1. The member/enrollee is mobile within the home or community;
    - 2. The qualifying blood gas study was performed while at rest (awake) or during exercise. (If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not reasonable and necessary).
- **IV.** It is the policy of health plans affiliated with Centene Corporation that reauthorization of oxygen concentrators and other supplemental oxygen delivery systems for members/enrollees < 18 years of age (including medically fragile members/enrollees and those covered by EPSDT) are medically necessary when meeting all of the following:
  - A. Evaluation by the treating physician within 30 days prior to the date of recertification;
  - B. One of the following:
    - 1. A new recorded (overnight recommended) pulse oximetry tracking, sleep study report, or blood gas result documents that the member/enrollee still meets the initial authorization criteria in Section II above, and the measurement meets both of the following:

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- a. Obtained within 30 days of the recertification date;
- b. Obtained by the physician or designee, or by an independent diagnostic testing facility (IDTF). DME companies are prohibited from obtaining the O<sub>2</sub> levels unless they are also home oxygen providers. Home oxygen companies are permitted to coordinate with an IDTF for the purpose of obtaining needed overnight oximetry saturation testing;
- 2. Chronic hypoxemia is not expected to resolve or is expected to worsen, as documented in an explanatory letter of medical necessity (LOMN);
- C. If request is for a portable oxygen system, member/enrollee is mobile within the home or community.<sup>7</sup>
- V. It is the policy of health plans affiliated with Centene Corporation that oxygen concentrators are not medically necessary for the following indications<sup>1,3,8</sup>:
  - A. Angina pectoris in the absence of hypoxemia;
  - B. Breathlessness without cor pulmonale or evidence of hypoxemia;
  - C. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia;
  - D. Shortness of breath or dyspnea in a pediatric patient without evidence of hypoxemia;
  - E. Terminal illnesses that do not affect the ability to breathe. 1,8
- VI. It is the policy of health plans affiliated with Centene Corporation that stationary gaseous oxygen systems (i.e. cylinder of liquid or gaseous oxygen) and related delivery equipment for the treatment of cluster headaches are **medically necessary** when meeting the following:
  - A. Diagnosis of cluster headache as evidenced by all of the following<sup>7,10,11,12,13</sup>;
    - 1. At least five severe to very severe unilateral headache attacks lasting 15 to 180 minutes when untreated;
    - 2. The headaches are accompanied by at least one of the following:
      - a. Ipsilateral conjunctival injection and/or lacrimation;
      - b. Ipsilateral nasal congestion and/or rhinorrhea;
      - c. Ipsilateral eyelid edema;
      - d. Ipsilateral forehead and facial sweating;
      - e. Ipsilateral miosis and/or ptosis;
      - f. A sense of restlessness or agitation;
    - 3. Frequency of headache attacks occur between one every other day and eight per day.<sup>11</sup>

#### **Background**

Oxygenation is the process of oxygen diffusing passively from the alveolus to the pulmonary capillary, where it binds to hemoglobin in red blood cells or dissolves into the plasma.<sup>2</sup> A low partial pressure of oxygen in the blood is termed hypoxemia. Hypoxemia can have multiple causes including hypoventilation, ventilation-perfusion (V/Q) mismatch, right-to-left shunts, diffusion limitation, and reduced inspired oxygen tension. Common tests to determine if oxygenation is impaired and at risk of being insufficient include arterial oxygen saturation (SaO<sub>2</sub>), arterial oxygen tension (PaO<sub>2</sub>), alveolar to arterial (A-a) oxygen gradient, and the PaO<sub>2</sub>/fraction of inspired oxygen (FiO<sub>2</sub>) ratio.<sup>2</sup>

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Indications for continuous long-term oxygen therapy (LTOT) for those with chronic lung disease include<sup>3</sup>:

- Resting arterial oxygen tension (PaO<sub>2</sub>) less than or equal to 55 mmHg (7.32 kPa), or a pulse oxygen saturation (SpO<sub>2</sub>) less than or equal to 88 percent;
- PaO<sub>2</sub> less than or equal to 59 mmHg (7.85 kPa), or an SpO<sub>2</sub> less than or equal to 89 percent, if there is evidence of cor pulmonale, right heart failure, or erythrocytosis (hematocrit >55 percent);
- PaO<sub>2</sub> of 55 mmHg (7.32 kPa) or lower, or an SpO<sub>2</sub> of 88 percent or lower, during exercise or sleep.

Prescribed oxygen flow rates may vary throughout the day with activity or sleep or during acute exacerbations of disease. For patients with nocturnal oxygen desaturation, clinical evaluation for sleep-disordered breathing utilizing polysomnography are often appropriate.<sup>3</sup>

#### The American Association for Respiratory Care

According to the American Association for Respiratory Care LTOT in the home or alternate site health care facility is normally indicated for the treatment of hypoxemia and has been shown to have a significant positive impact on hypoxemic patients with chronic obstructive pulmonary disease (COPD). LTOT has also been shown to reduce hospitalizations and lengths of stay. Laboratory indications for LTOT include documented hypoxemia in adults, children, and infants older than 28 days as evidenced by  $PaO_2 \le 55$  mm Hg or  $SaO_2 \le 88\%$  in subjects breathing room air or  $PaO_2$  of 56 to 59 mm Hg or  $SaO_2$  or  $SpO_2 \le 89\%$  in association with specific clinical conditions such as cor pulmonale, congestive heart failure, or erythrocythemia with hematocrit > 56. Some patients may not demonstrate a need for oxygen therapy at rest but will be hypoxemic during ambulation, sleep, or exercise. Oxygen therapy is indicated during these specific activities when the  $SaO_2$  is demonstrated to fall to  $\le 88\%$ . The initial need for LTOT is determined by measurement of inadequate arterial blood oxygen tensions and/or saturations and/or the presence of clinical indicators. Ongoing evaluation or reassessment of arterial blood gas tensions and/or saturations by invasive or noninvasive methods may be indicated whenever there is a change in clinical status that may be cardiopulmonary related.\frac{1}{2}

### The American Thoracic Society

Per the American Thoracic Society Clinical Practice Guidelines for Home Oxygen Therapy (HOT) in Adults, HOT is recommended for the following:<sup>4</sup>

- For patients with severe resting hypoxemia, the prescription of LTOT to improve survival is supported by historical trials in patients with COPD;
- The expert panel strongly recommends prescribing oxygen for patients with interstitial lung disease (ILD) with severe resting hypoxemia;
- Existing evidence and panel consensus suggest not prescribing LTOT for patients with COPD with moderate resting hypoxemia;
- This review confirmed scarce and inconclusive data to support the prescription of oxygen in patients who have normoxia at rest but desaturate (sometimes markedly) with exertion;
- Emerging evidence suggests that ambulatory oxygen therapy may improve health-related quality of life in patients with ILD in the short term but longer-term data are needed;
- The panel unanimously agreed that liquid oxygen (LOX) should be offered to active patients on high-flow oxygen;

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 Finally, the minimal standard of care for all patients receiving home oxygen therapy must include education and training related to their oxygen equipment, oxygen safety, and selfmanagement.

The American Thoracic Society Clinical Practice Guidelines for Home Oxygen Therapy in Children states that, despite widespread use of home oxygen therapy (HOT) in children for various lung and pulmonary vascular diseases, there is a striking paucity of data regarding its implementation, efficacy, monitoring, and discontinuation. With limited evidence, the panel provides recommendations based on expert opinion and experiences associated with patient-important outcomes, which will aid clinicians in the management of complex pediatric patients requiring HOT.<sup>5</sup>

HOT for children is recommended for the following situations<sup>5</sup>:

- Cystic fibrosis complicated by severe chronic hypoxemia (strong recommendation, very low-quality evidence);
- Cystic fibrosis patients who have both mild chronic hypoxemia and dyspnea on exertion (conditional recommendation, very low-quality evidence);
- Bronchopulmonary dysplasia complicated by chronic hypoxemia (strong recommendation, very low-quality evidence);
- Sleep-disordered breathing complicated by severe nocturnal hypoxemia in those who cannot tolerate positive airway pressure therapy or are awaiting surgical treatment of sleep-disordered breathing (conditional recommendation, very low-quality evidence);
- Sickle cell disease complicated by severe chronic hypoxemia (conditional recommendation, very low-quality evidence);
- Pulmonary hypertension without congenital heart disease complicated by chronic hypoxemia (strong recommendation, very low-quality evidence);
- Interstitial lung disease complicated by severe chronic hypoxemia (strong recommendation, very low-quality evidence);
- Interstitial lung disease patients who have mild chronic hypoxemia and either dyspnea on exertion or desaturation during sleep or exertion (conditional recommendation, very low-quality evidence):
- Pulmonary hypertension with congenital heart disease complicated by chronic hypoxemia but not until there has been consultation with a pediatric pulmonologist or cardiologist who has expertise in the management of pulmonary hypertension in this clinical setting, regardless of previous reparative or palliative congenital heart surgery (strong recommendation, very low-quality evidence).

Additionally, the expert panel unanimously agreed that optimal implementation of the above HOT recommendations consists of all of the following<sup>5</sup>:

- Oxygen therapy to maintain an oxygen saturation as measured by pulse oximetry in an
  acceptable range according to age and respiratory condition outlined in the full guideline
  document;
- Use of oxygen equipment that is of the appropriate size, developmental stage, and flow rate to function properly;
- Oxygen therapy monitoring by pulse oximetry in the home.



#### **Coding Implications**

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HCPCS	Description				
Codes					
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing				
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing				
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing				
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing				
E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge				
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing				
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor				
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing				
E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing				
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit				
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit				
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit				
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit				
E0445	Oximeter device for measuring blood oxygen levels noninvasively				
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate				
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each				
E1392	Portable oxygen concentrator, rental				
E1405	Oxygen and water vapor enriching system with heated delivery				
E1406	Oxygen and water vapor enriching system without heated delivery				



HCPCS	Description
Codes	
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing
S8120	Oxygen contents, gaseous, 1 unit equals 1 cubic foot
S8121	Oxygen contents, liquid, 1 unit equals 1 pound

Reviews, Revisions, and Approvals		Approval
Policy developed	Date 05/20	Date
Noted in reauthorization criteria for Group 1 that nocturnal hypoxemia doesn't have to have a qualifying ABG or pulse ox after the first two approvals. Added that a DME company cannot provide the reauthorization pulse ox test, but an independent diagnostic testing facility (IDTF) can, and a home oxygen company can coordinate with an	07/20	07/20
IDTF to do so also. Added criteria for portable oxygen systems in IV.  In sections I and III, clarified that the criteria applies to stationary oxygen systems as well as portable oxygen systems. In section II: specified that the diagnosis list is not all-inclusive, and that there be a cause of severe lung disease or hypoxia; edited diagnosis list; added polysomnography as a qualifying lab results option. Specified that reauthorization criteria in section III applies to adults. Added reauthorization criteria for age <21 years in section IV. Portable oxygen systems: Added that criteria in section I. must be met and specified that portable oxygen system criteria applies to adults. Added "shortness of breath or dyspnea in a pediatric patient without evidence of hypoxemia" to the list of not medically necessary indications for oxygen concentrators. Removed accessory codes. Replaced "members" with "members/enrollees" in all instances.	09/20	09/20
Clarified in I.2.a. that the oxygen saturation should be 89% or less, instead of 89%.	10/20	
For reauthorization of oxygen concentrators and stationary oxygen systems in adults in section III, added an option for a letter of medical necessity documenting a chronic condition not expected to improve or expected to worsen, when provided in addition to a physician evaluation within 90 days. Clarified that both the Group 1 re-auth criteria in section III.A.2.a need to be met. Restructured section III with minor rewording. Specified that section I. applies to oxygen concentrators and stationary oxygen systems for indications other than cluster headaches, and referred to section VII for stationary oxygen systems for cluster headaches. Specified in section VII that the criteria for cluster headaches applies to those ≥ 21 years.	11/20	11/20
Annual review. References reviewed and updated. Background updated.	09/21	09/21



Changed "review date" in the header to "date of last revision" and "date"		
in the revision log header to "revision date." Reviewed by specialist.		
Edited portable oxygen criteria to include option for "mobile within	10/21	10/21
community" in addition to "within the home." Reorganized portable		
oxygen criteria within sections I and III. Added criteria for portable		
oxygen systems for pediatrics in sections II and IV.		
In the over 21 auth and reauth sections regarding the qualifying blood	11/21	
gas study for portable oxygen and concentrators, removed "for the		
approved stationary concentrator" for clarity.		
Annual review. References reviewed and updated. Coding Verified.	01/22	01/22
Annual review. Updated title from Oxygen Use and Concentrators to	01/23	01/23
Outpatient Oxygen Use. Added "Note: If a medically necessary, lesser		
cost item exists and will suit the member/enrollee's medical needs, a		
higher cost item will be denied." under the Description section. In I.A.		
updated "hypoxia" to "hypoxemia." Updated statement and included		
reference (based on CMS NCD 240.2) <sup>8</sup> to I.B.1. and I.B.2 for clarity. In		
II.A. updated "hypoxia" to "hypoxemia." In III.A.2. added "criteria" to		
(as defined in criteria section I) statement for clarity. In IV.B.2. changed		
Chronic hypoxemia is not expected to "improve" to "resolve." In VI.		
added "(i.e. cylinder of liquid or gaseous oxygen)" and related "delivery		
equipment" for clarity and removed age criteria "\ge 21." Reformatted		
criteria in VI.A.1. and 2 for clarity. Removed VI.B. "Enrolled in clinical		
trial" Minor rewording with no clinical significance. Background		
updated with no clinical significance. References reviewed and updated.		
Internal and external specialist reviewed.		
Annual review. Changed age requirements in I and III from ≥ 21 to ≥	01/24	
	01/24	
18 years of age. Changed age requirements in II and IV from <21 to <18		
years of age. Minor rewording in Criteria I. Added clarifying language to		
Criteria I.B.1.a. regarding breathing room air. In I. B.1.b., I.B.1.c., and		
I.B.2.a., removed the requirement that the measurement is taken after 5		
minutes of sleep vs. during sleep. Criteria I.D.2. updated to reflect		
condition requirements for blood gas study not performed during an		
inpatient hospital stay. Removed I.E. regarding alternative treatments.		
Added clarifying language to Criteria II.A.2. for cystic fibrosis		
complicated by severe chronic hypoxemia. Updated Criteria II.A.4. to		
state Bronchopulmonary dysplasia (BPD) complicated by chronic		
hypoxemia. Added Criteria II.A.9. to include pulmonary hypertension		
without congenital heart disease complicated by chronic hypoxemia.		
Added Criteria II.A.10. to include interstitial lung disease complicated		
by severe chronic hypoxemia. Updated Criteria II.B.1. and Criteria		
II.B.2. to include requirements for SpO <sub>2</sub> measurements for children		
younger than one year old and for children aged one year or older. Minor		
rewording in Criteria III.A.3.a. and Criteria III.A.3.b. Minor rewording		
to Criteria IV.B.1. Clarifying language added to Criteria V.C. regarding		
the absence of systemic hypoxemia. Added Criteria V.E. to include		
terminal illnesses that do not affect the ability to breathe. Minor		

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rewording in Criteria VI. Added Criteria VI.A.3. to include frequency of headache attacks. Background updated with no impact on criteria.	
References reviewed and updated.	

#### References

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https://www.nice.org.uk/guidance/cg150/chapter/Key-priorities-for-implementation. Published September 19, 2012 (Updated December 17, 2021). Accessed January 10, 2024.

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions



expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note:** For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <a href="http://www.cms.gov">http://www.cms.gov</a> for additional information.

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